

Expert Guide

InsurTech challenges in Europe

February 2023

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Introduction



Given the huge growth of the industry in recent years, it has become challenging to define the scope of the Insurtech sector. For the purposes of this guide, we regard Insurtechs as those companies related to the insurance sector that employ digital tools and technology solutions for innovation, to create new business models and in transforming the value chain.

Examples of this type of disruption in this field include Big Data, the internet of things (IoT), mobile technology, artificial intelligence and blockchain solutions, along with innovative use of web platforms or mobile applications.

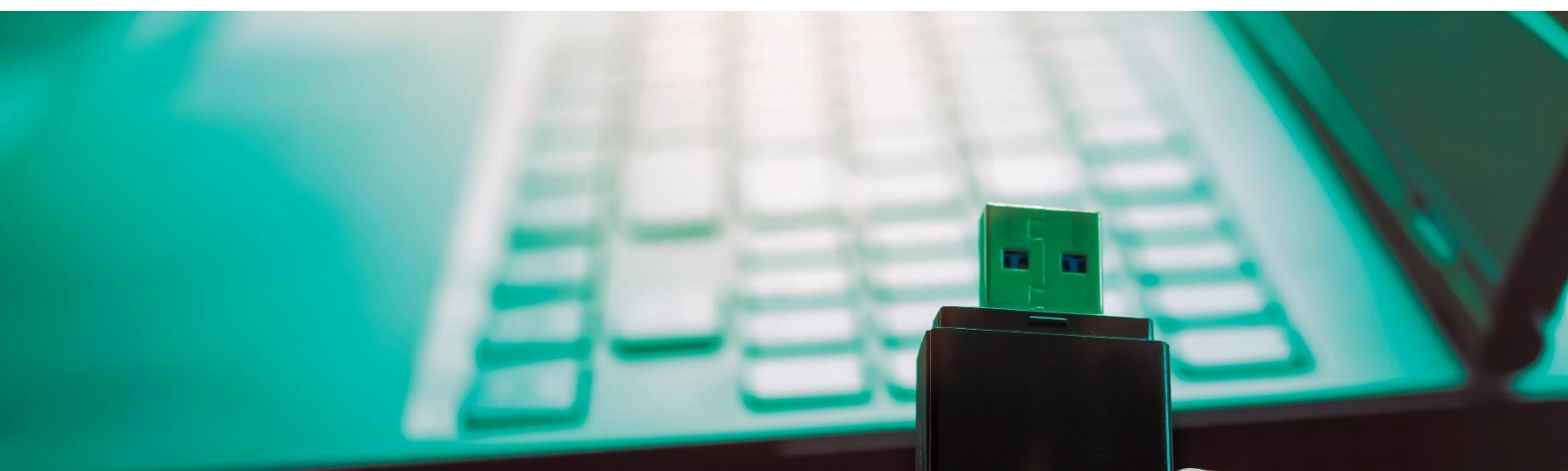
Although new disruptors bring distinct advantages and are constantly evolving to meet the demands of the industry and its customers, they must still adapt to the shifting regulatory environment, specifically the new insurance distribution directive came into force.

The main purpose of this Guide is to shed light on the outstanding challenges that stem from the rules on insurance distribution and digitalisation technologies. It is designed to better position Insurtechs to successfully operate in the insurance market so that the industry and customers can benefit from these technological and innovative advances.

This guide has been prepared with a view to ongoing and future disruption by these new players, such as Insurtechs, such that the CMS specialists have relied on the regulatory items exhaustively listed in Legal schedule .

This Expert Guide has been prepared by the following teams:

| | |
|-------------------|----------------|
| — CMS Belgium | — CMS Portugal |
| — CMS France | — CMS Ukraine |
| — CMS Italy | — CMS UK |
| — CMS Netherlands | — CMS Spain |



Glossary

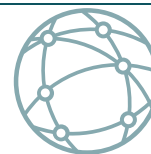


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|------------------------|--|
| ACPR | <i>Autorité de contrôle prudentiel et de résolution</i> , French Prudential Supervision and Resolution Authority. |
| AEPD | <i>Agencia Española de Protección de Datos</i> , national supervisory authority in Spain on data protection. |
| AFM | <i>Autoriteit Financiële Markten</i> , the Dutch supervisory authority. |
| AI | Artificial Intelligence. |
| AML | Anti-Money Laundering. |
| API | Application Programming Interfaces, meaning the connecting nodes of the digital society, thus a foundational component of its digital transformation. |
| ASF | <i>Autoridade de Supervisão de Seguros e Fundos de Pensões</i> , the national supervisory authority in Portugal. |
| CBb | Dutch Trade and Industry Appeals Tribunal. |
| CDO | Chief Data Officer. |
| CMVM | <i>Comissão do Mercado de Valores Mobiliários</i> , the Portuguese securities market commission. |
| Code of Conduct | A compilation of standards based on underlying principles of good conduct. This basis may relate back to the industry's values and tie to what constitutes best practices in the market. |
| Digital identification | The electronic and traceable identification of natural or legal persons, aimed at sharing the necessary identity data and electronic attestation of attributes to authenticate online and offline, in order to use or access public and private cross-border services in a trusted and seamless way. |
| DNB | <i>De Nederlandsche Bank</i> , the Dutch central bank |
| DPA 2018 | United Kingdom Data Protection Act 2018 |
| EBA | European Banking Authority |
| eIDAS | Regulation 910/2014 on electronic identification and trust services for electronic transactions in the internal market |
| EIOPA | European Insurance and Occupational Pensions Authority |
| ESAs | European Supervisory Authorities (EIOPA, ESMA and EBA) |

| | |
|---|--|
| ESMA | European Securities and Markets Authority |
| FCA | Financial Conduct Authority, the national supervisory authority in UK. |
| FOS | Freedom of Establishment or Freedom to Provide Services |
| FSMA | Belgium Financial Services and Markets Authority |
| GDPR | Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) |
| ICOBS | Insurance Conduct of Business Sourcebook issued by the FCA, the Supervisory Authority in the United Kingdom. |
| IDD or Insurance Distribution Directive | Directive (EU) 2016/97 of the European Parliament and of the Council on insurance distribution. |
| IoT | Internet of things |
| IVASS | <i>Istituto per la Vigilanza sulle Assicurazioni</i> , the national supervisory authority in Italy. |
| JRC | Commission's Joint Research Centre |
| KYC | French customer identification procedure |
| ML | Machine Learning |
| MLRs 2017 | United Kingdom Terrorist Financing and Transfer of Funds (Information on the Payer) Regulations 2017 |
| NIR | French National Identification Registry |
| PECR | United Kingdom's Privacy and Electronic Communications Regulations |
| PSD2 | Directive (EU) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on Payment Services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC |
| Obisal | Spanish Observatory on the Social Impact of Algorithms |
| On-boarding | By means of the use of interoperable digital identity solutions, the process by which new customers are enabled to access financial services, within this context, insurance products. |
| Open insurance | According to EIOPA, in the broadest sense, it covers accessing and sharing insurance-related personal and non-personal data usually via APIs. |
| RUI | Italian Register of Insurance Intermediaries |

| | |
|--------|---|
| SEPLAC | Spanish Executive Service of the Commission for the Prevention of Money Laundering and Monetary Offences |
| SPID | Italian Public Digital Identity System |
| UNESPA | Spanish insurers' Association. |
| WFT | Dutch Financial Supervision Act, in Dutch: Wet op het financieel toezicht |
| WWFT | Dutch Anti-Money Laundering and Anti-Terrorist Financing Act, in Dutch: <i>Wet ter voorkoming van witwassen en financieren van terrorisme</i> |

Regulatory mapping on jurisdictions



| Country | Online selling | | | New technologies | | Digital identity and digital onboarding | Concerns on data protection | Open insurance | Big data |
|-----------------|----------------------|---|--|--|-------------------------|---|-----------------------------|----------------|----------|
| | Regulatory framework | Different ruling than conventional distribution | Specific ruling on online insurance payments | Machine Learning and Artificial Intelligence | Rules on Blockchain use | | | | |
| Belgium | ✓ | ✓ | ✗ | ✗ | ✗ | ✓ | ✓ | ✗ | ✓ |
| France | ✓ | ✓ | ✗ | ✗ | ✗ | ✓ | ✓ | ✗ | ✓ |
| Italy | ✓ | ✓ | ✗ | ✗ | ✗ | ✓ | ✓ | ✗ | ✗ |
| Portugal | ✓ | ✓ | ✗ | ✗ | ✗ | ✓ | ✓ | ✗ | ✓ |
| The Netherlands | ✓ | ✓ | ✗ | ✓ | ✗ | ✓ | ✓ | ✗ | ✓ |
| Ukraine | ✓ | ✓ | ✗ | ✗ | ✗ | ✓ | ✓ | ✗ | ✗ |
| United Kingdom | ✓ | ✓ | ✗ | ✗ | ✓ | ✓ | ✓ | ✗ | ✗ |
| Spain | ✓ | ✓ | ✗ | ✓ | ✓ | ✓ | ✓ | ✗ | ✓ |



Insurtech in Europe | Practices and Legal Fact Book



1. Online selling

1.1 Regulatory framework

Belgium

Observing the latest regulatory developments on insurance digital distribution, it is notable that the Belgian regulator has not made a specific distinction between online distribution and “traditional” distribution. When carrying out online distribution, the legislation on distance financial contract and the 2002 act on information society services and electronic commerce must be still applicable.

France

Digital distribution of insurance products is not subject to any specific regulation in France, and is therefore governed by:

- the general provisions of the French insurance code, ruling on insurance distribution and implementing the *Directive (EU) 2016/97 of the European Parliament and of the Council of 20 January 2016 on insurance distribution* (“IDD”) in France; and
- additionally, legal provisions provided by the legal framework given by French consumer code, implementing the *2002/65/EC Directive on the distance marketing of consumer financial services* apply to online intermediation activities.

Italy

Italian authorities have developed a strong focus on in the Insurtech industry. The *Istituto per la Vigilanza sulle Assicurazioni* (“IVASS”) is in fact one of the players in the “regulatory sandbox”. This is a project implemented by the Ministry of Economy and Finance, in collaboration with the Bank of Italy and the *Commissione Nazionale per le Società e la Borsa*, public authority responsible for regulating the Italian financial markets (“CONSOB”), coming into force via the *Decree of the Ministry of Economy and Finance No. 100 of 30 April 2021* (“MEF Implementing Decree”). It is a controlled environment in which traditional and Fintech / Insurtech operators will be able to test technologically innovative products and services, benefiting from a simplified transitional regime. Through the sandbox, IVASS will be able to observe the dynamics of technological development and identify the most appropriate and effective regulatory measures to facilitate the development of Insurtech, reducing the spread of potential risks associated with these activities.

IVASS also took some regulatory actions in 2021 which affected remote distribution players. For example, as of the second quarter of this year, intermediaries operating under Freedom of Services (“FOS”) can no longer register their collaborators in the Register of Insurance Intermediaries (“RUI”). IVASS has clarified that the presence of collaborators in Italy is, in fact, considered to be a typical element of the different FOS regime. This means that if EU intermediaries, in addition to distributing purely online, wish to engage external collaborators in Italy, they will need to establish a branch office and identify a responsible person.

Portugal

Currently there is no specific regulation regarding insurance digital distribution and the rules foreseen for the traditional insurance distribution Law no. 7/2019 and the Regulatory Rule nº 13/2020-R of the *Autoridade de Supervisão de Seguros e Fundos de Pensões* (“ASF’s”), the national supervisory authority in Portugal, should apply.

The ASF has demonstrated an open and receptive approach to technology and innovation in the insurance market. For example, ASF together with Bank of Portugal (the “central bank of Portugal”), *Comissão do Mercado de Valores Mobiliários*, Portuguese Securities Market Commission. (“CMVM”) (and Portugal Fintech Association launched the “Portugal FinLab”, a platform that aims to develop the FinTech, Insurtech and RegTech network in Portugal. It is designed to establish efficient communication channels between innovative start-ups/companies and regulators with a view towards the implementation of innovative projects. ASF considers that such a platform has major importance for the supervisory authorities as it allows them to monitor and be aware of new digital challenges, to protect consumers and to anticipate regulatory issues that may arise.

The Netherlands

The Dutch regulator has not made a specific distinction between online/digital distribution and “traditional” distribution of insurance products. In both cases the requirements following from the European Insurance Distribution Directive do apply, which is mainly implemented in the Netherlands into the Dutch Financial Supervision Act (in Dutch: “*Wet op het financieel toezicht*” – WFT) and the lower rules and regulations promulgated thereunder.

In addition, the insurance related provisions following from Book 7 of the Dutch Civil Code (in Dutch: “*Burgerlijk Wetboek*”) do apply to both online/digital distribution and “traditional” distribution of insurance products.



Nevertheless, when carrying out online/digital distribution activities, the following complementary legislation must be taken into consideration:

- certain provisions following from Book 6 of the Dutch Civil Code on distant and off-premises agreements (consumer rights);
- certain provisions following from the Decree on Conduct of Business Supervision of Financial Undertakings (in Dutch: *Besluit Gedragstoezicht financiële ondernemingen*) dealing with distance insurance agreements.

Ukraine

The existing Ukrainian legislation does not regulate insurance digital distribution, but distribution is not prohibited. For digital distribution, it is important to ensure that insurers and their counterparties comply with general rules for distribution of insurances (the Law of the Ukraine “On Insurance”, adopted on 7 March 1996 under No. 85/96-BP) and general requirements of Ukrainian law when entering into insurance agreements (e.g., for proper execution by electronic signature).

In addition, the National Bank of Ukraine, as regulator, has recently declared that digitalisation of financial markets will be one of its priorities, which implies further regulatory developments in this field. There are several expectations regarding the introduction of new regulations on insurance digital distribution in the near future.

United Kingdom

The United Kingdom (UK) regulator has not made a specific distinction between online distribution and “traditional” distribution. The UK regulator’s approach tends to be technology neutral, focussing instead on delivering good customer outcomes.

The rules concerning insurance distribution are primarily set out in the Insurance Conduct of Business Sourcebook (“ICOB”) sourcebook of the Financial Conduct Authority, national supervisor authority in the United Kingdom (“FCA”) Handbook, which incorporates certain requirements concerning distance marketing and e-commerce activity. Firms should also have regard to the Financial Services and Markets Act 2000 (Financial Promotion). Order 2005 and the Consumer Rights Act 2015.

As regards recent regulatory developments, the UK regulator has, from 1 January 2022, introduced rules concerning the pricing of new and renewing insurance products and the operation of renewals. Firms should also be aware of the forthcoming Consumer Duty which will be implemented in 2023 require retail firms to: (i) consider what outcomes customers should expect from products and services; (ii) act to enable such outcomes; and (iii) assess the effectiveness of their actions.

It should be noted that the UK regulator takes an open and proactive approach to the use of new technologies and has launched an Innovation Hub which seeks to encourage and support innovation in financial services. Firms offering innovative products and/or services may have access to a range of services from the UK regulator, including access to a digital sandbox, a regulatory sandbox, a specialist automated advice unit, and the ability to undertake cross-border testing.

Spain

Insurance distribution is regulated by Royal Legislative Decree, 3/2020, on urgent measures, which transposes into Spanish law various European Union directives in the field of public procurement in certain sectors; private insurance; pension plans and funds; taxation and tax litigation.

Nevertheless, when carrying out online distribution the following complementary legislation must be taken into consideration:

- Law 22/2007 of 11 July 2007 on distance marketing of consumer financial services;
- Royal Legislative Decree 1/2007, approving the revised text of the General Law for the Defence of Consumers and Users and other complementary laws;
- Law 34/2002 2002 on information society services and electronic commerce.

1.2 Differences with conventional distribution channels

Belgium

Both, traditional and digital distribution channels are regulated by the same regulations in Belgium.

However, as the legislator is aware of the need to provide additional protection in the case of online contracting, there are certain particularities that are reinforced, such as the pre-contractual information duties, the right of withdrawal, the provision of non-requested services, etc.

France

The only relevant regulatory difference with traditional distribution, which is not specific to online selling but is common to all means of distance selling of insurance products, is the right of withdrawal of the consumer policyholder within a 14-day timeline following the conclusion of the contract (or, if later, the reception of precontractual information and contractual terms and conditions on a durable medium).

Italy

Current regulatory frameworks do not distinguish digital and so-called traditional distribution.

Nevertheless, the Italian legislator requires some additional precautions aiming at protecting the user/consumer when insurance products are sold at distance or online. For example, the distributors have more intense pre-contractual information duties, the consumers have a right of withdrawal bylaw, it is forbidden the provision of non-requested services etc.

Portugal

Both digital and traditional distribution are essentially subject to the same rules.

However, in respect of digital distribution it should be also considered the legal framework applicable to contracts negotiated at distance (Decree Law no. 95/2006, transposing the Directive concerning distance marketing of consumer financial services). This legal framework establishes reinforced duties of information in respect of: i) the insurance intermediaries; ii) the insurance contract; and iii) the protection mechanisms available (out-of-court means of dispute resolution and the existence of guarantee funds or other compensation arrangements). These duties need to be fulfilled prior to the conclusion of the insurance

contract and to be provided in a durable medium. In addition, it is also foreseen a general rule granting the consumer's right of free termination of the contract, without giving any reason and without any kind of penalty, within a period of 14 or 30 days, as applicable, from the date of conclusion of the insurance contract.

The Netherlands

As both distribution channels are basically regulated by the same legal framework, the essential core of both remains the same.

However, if an insurance is distributed through online rather than through traditional channels, there are certain particularities that need to be taken into account, such as, for example, a wider range of pre-contractual information duties and the right of withdrawal.

Ukraine

Current regulatory framework does not clearly distinguish digital and so-called traditional distribution.

However, companies should take into account the e-commerce legislation, which applies to retail customers (not B2B) and sets out rules for conclusion of contracts via digital means. It provides an opportunity to express offer and acceptance using e-messages/e-letters and conclude insurance contracts using a digital signature. At the same time, it requires for certain detailed disclosures of information at the time of e-offer and must be aligned with general insurance legislation.

United Kingdom

Both distribution channels are regulated by the same rules.

However, firms should consider the rules concerning distance marketing and e-commerce activities (each of which is covered in ICOBS 3 in the FCA Handbook), which generally stress the need to make sufficient disclosures and ensure that key information is provided in a durable medium.

Spain

Insurance Online distribution also is governed by provisions of Law 22/2007, of 11 July 2007, on distance marketing of consumer financial services. This law establishes several requirements for online distribution, including the need to provide additional precontractual information to customers.

As regards right of withdrawal, this law includes longer time limits for consumer withdrawal, allowing it within a period of up to one month.

Likewise, under this rule online distributors are not allowed to communicate and provide services not requested by the consumer, and therefore the express consent of the consumer is required in all cases.

Nevertheless, the legislator is aware of the need to provide additional protection in the case of online contracting, as the current law dates before 2007.

1.3 Online payment services

Belgium

There is currently no specific insurance regulation on online payments, so transposing legislation of the Directive (Eu) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on Payment Services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC ("PSD2") is fully applicable.

France

There is no specific regulation applicable to online payments for insurance products.

Therefore, the banking regulations of PSD and PSD2 under the French monetary and financial code, apply to online payments.



Italy

No further rules specifying main issues concerning insurance companies and intermediaries regarding online payments in insurance in the context of online distribution and Insurtech besides what regulated by European Union law.

Portugal

There is no specific regulation relating to online payments of insurance products. However, the following regulations are fully applied:

- Decree Law no. 7/2004, which regulates the Legal Framework for Electronic Commerce (transposing the Directive (EU) 2000/31/CE, of the European Parliament and of the Council);
- Decree Law no. 91/2018, which regulates the Legal Framework for Payment Services and Electronic Currency (transposing the Payment Services Directive (EU) 2015/2366 of the European Parliament and of the Council).;
- Decree Law no. 109-G/2021, (transposing partially the Directive (EU) 2019/2161 of the European Parliament and of the Council, with respect to better enforcement and modernisation of Union consumer protection rules, namely regarding online purchase of products). Please note that this regulation entered into force on 28 May 2022.



The Netherlands

There is currently no specific regulation on online payments for insurance products in the Netherlands. Generally digital payments in the Netherlands are covered by the requirements following from the PSD2, which is mainly implemented in the Netherlands into the Dutch Financial Supervision Act (including the lower rules and regulations promulgated thereunder) and the Dutch Civil Code.

Ukraine

There are no specific regulations related to online payments for insurance products.

The insurance payments fall under the general regulation of the Law of Ukraine “On Payment Systems and Funds Transfer in Ukraine”

No. 2346-III, dated 5 April 2001, which relatively soon will be replaced by the new Law of Ukraine “On Payment Services” 1591-IX, becoming effective on 1 August 2022.

United Kingdom

There is currently no regulation relating specifically to online payments of insurance products, but Payment Services Regulations 2017/752 (transposing the PSD2), is fully applicable.

Spain

There is currently no specific insurance regulation on online payments, so Royal Legislative Decree 19/2018, on payment services and other urgent measures in financial matters, transposing the PSD2, is fully applicable.

2. NEW TECHNOLOGIES

2.1 Machine learning and Artificial Intelligence

Belgium

For the moment, the legal framework covering insurance industry activity does not regulate the use of Artificial Intelligence (“AI”) or machine learning (“ML”).

France

For the moment, French legislation does not regulate the use of AI or machine Learning. Parliamentary reports have been published but have not yet been followed by any action.

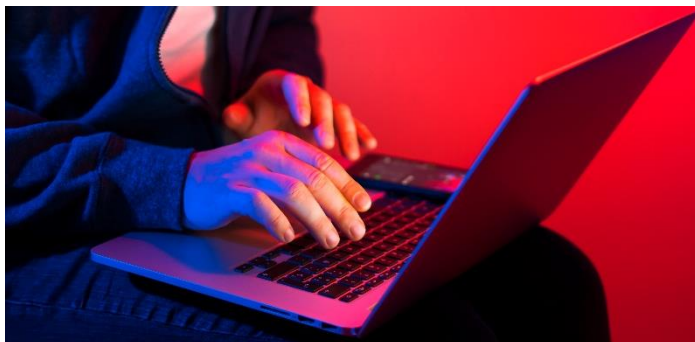
Italy

Several points have been debated, such as the standardisation of customer identification procedures or those for signing contracts online. In addition, while the use of new technologies such as AI, blockchain or Application Programming Interfaces, meaning the connecting nodes of the digital society, thus a foundational component of its digital transformation (“APIs”) is increasingly widespread, there is still no official guidance from the authorities and neither from the legislator on the correct use of such tools. IVASS has recently launched a consultation on the use of machine learning algorithms in insurance sector.

Portugal

Currently there is no specific insurance regulation relating to the use of machine learning and AI nor any sectorial code of conduct on this matter.

Consequently, when deploying these technologies in the development and distribution of insurance products, entities should be mindful of their duty to act in customers’ best interests and be in compliance with the information duties, in accordance with the Consumer Act (Law no. 24/96, of 31 July 1996), namely fairness and transparency principles.



The European Insurance and Occupational Pensions Authority (“EIOPA”) has published a report on digital ethics setting out AI governance principles for an ethical and trustworthy AI in the European insurance sector. Thus, being mostly principles-based, this document sets forth the key elements for implementing the impact assessments within AI- driven tools in Insurance.

Additionally, the EU’s proposal on AI Regulation which is expected to come into force during 2022, should be taken into account. This sets the grounds for a risk-based approach towards AI applications, which must, consider the high risks, automation and optimised pricing approaches in the insurance sector.

The Netherlands

On 25 July 2019, the Dutch supervisory authorities and the Dutch Central Bank, in Dutch “*Autoriteit Financiële Markten*” (“AFM”) and *De Nederlandsche Bank* (“DNB”), have jointly published an exploratory study on “Artificial intelligence in the insurance sector”. The study contains 10 points of consideration when applying AI in the insurance sector.

Furthermore, DNB published in April 2020 its “Theme research Insurtech”, in which it outlines the results of an inventory of Insurtech within small and medium-sized companies. DNB considers it important that insurers are aware of the potential opportunities and risks of Insurtech.

On 26 January 2022, DNB announced that due to the quick technological developments it will continue to follow AI developments, with respect to the insurance sector. The DNB project “AI and rationale” will be

continued in 2022, and DNB will be actively involved in international meetings about AI, for example, via EIOPA.

Ukraine

There is currently no specific legislation, guidance from the authority, or code of conduct regulating the use of ML or AI.

United Kingdom

At present, there is no specific insurance regulation relating to the use of machine learning and AI nor any specific code of conduct.

The UK regulator has recognised the benefits of digital innovation for consumers, including those offered by machine learning and AI, and has stressed the need for transparent, fair, secure and ethical use of such technologies. It has established an AI Public-Private Forum which seeks to support the safe adoption of these technologies within financial services and to consider whether principles, guidance, regulation and or industry good practice could support this.

When using such technologies in the development and distribution of insurance products firms should be mindful of their duty to act in customers' best interests and the rules and guidance around ensuring fair value. The introduction of the new Consumer Duty in will also be pertinent to firms' use of machine learning and AI. The UK regulator has also stressed that firms using these technologies are expected to fully understand such technology and to have robust governance in place.

The UK regulator is supportive of innovation within financial services and its Innovation Hub offers various services to insurance market participants that are seeking to use technology such as machine learning and AI in an innovative manner. This includes access to a 'regulatory sandbox' in which new propositions may be tested in a live environment with relaxations to certain rules for a limited time.

It is also worth noting that the UK government published its National AI Strategy in September 2021. This sets out the UK's intent to become a world leader in AI based around the three pillars of investment, ensuring AI benefits all sectors and regions, and governance. This has a broader reach than the EU's AI Regulation but is less precise in its proposals.

Spain

The Spanish insurers' Association ("UNESPA") has created a Code named, "*Principles for the ethical use of AI in the insurance sector*", allows entities voluntarily adhere and comply with the principles contained in the Code.

Moreover, for Artificial Intelligence, the following developments may apply:

- Spain has proposed to the Commission to become a testing platform for the AI Regulation. Through a pilot test, the European standard would begin to be applied with certain companies or industry participants before it becomes mandatory, as a pilot test. Currently, the plan is in the negotiation phase with the Commission's Joint Research Centre ("JRC");
- On 14 July 2021, the Digital Rights Charter was issued by the Spanish Government, which is not regulatory in nature, but it proposes a reference framework and lays the groundwork for future regulations;
- During July 2022, the new Digital Agenda called "Digital Spain 2026" was issued, which includes a set of measures including the objective of promoting the transition to a data economy, guaranteeing security and privacy, and taking advantage of the opportunities offered by Artificial Intelligence;
- Also, in July 2021, the Government launched the Observatory on the Social Impact of Algorithms ("Obisal");
- Consequently, the following measures are foreseen to be developed: (i) National Artificial Intelligence Strategy; (ii) Data Office and Chief Data Officer ("CDO"); (iii) Artificial Intelligence Advisory Council; and (iv) Cloud Strategy: European shared data spaces.

2.2 Blockchain in insurance

Belgium

The use of blockchain in the insurance sector has not been specifically regulated.

France

The use of blockchain in the insurance sector has not been specifically regulated.

Italy

Although the use of new technologies such as AI, blockchain or APIs is increasingly widespread, there are still no rules approved nor official guidance given by the authorities governing the use of such tools within insurance distribution.

Portugal

Currently there is no specific insurance regulation relating to the use of blockchain in insurance nor any specific or sectorial code of conduct.

The EIOPA has published a Discussion Paper on Blockchain and Smart Contracts in Insurance. This comprises of a comprehensive guide on how these technologies might be deployed in the insurance sector and the specific and possible adverse effects on consumers.

Additionally, the Discussion Paper sets the ground for harmonising the European Approach to Blockchain and Smart Contracts in the Insurance sector.

The Netherlands

There is currently no specific insurance regulation, guidance or code of conduct on blockchain. Therefore, it is necessary to rely on the general regulation.

The application of blockchain technology must be incorporated into existing generic legislation on, for instance, securities law (e.g., Mifid implementation law) and Big Data regulations (e.g., GDPR).

Ukraine

There is currently no specific insurance regulation on blockchain.

On 8 September 2021, the Ukrainian parliament adopted Law of Ukraine “On Virtual Assets”, which aims to regulate all aspects of the circulation of virtual assets in Ukraine and can be viewed as a foundation for further development of blockchain regulations. However, this law will only become effective upon adoption of amendments to the Tax Code, which are not yet in place.

United Kingdom

At present, there is no specific insurance regulation relating to the use of blockchain in insurance nor any specific code of conduct.

The UK regulator has recognised the numerous potential benefits of blockchain technologies within the world of financial services but has stressed that it is for firms to determine how these can be adopted compliantly and to make sure the operational risks involved in the use of such technology are properly identified and mitigated.

However, to the extent an insurance product or service involves the use of cryptoassets (which are founded on blockchain technology), it should be noted that the UK regulator has expressed concerns about the potential for cryptoassets to result in consumer harm and has a dedicated Cryptoassets Taskforce. The UK regulator has taken a number of steps to address this, including: (i) publishing guidance within FCA Policy Statement CP19/22 clarifying the categorisation and treatment of cryptoassets within the UK regulatory regime; and (ii) banning the sale to retail clients of derivatives and exchange traded notes which reference certain types of cryptoassets.

The UK regulator is supportive of innovation within financial services and its Innovation Hub offers various services to insurance market participants that are seeking to use blockchain technologies in an innovative

manner. This includes access to a “regulatory sandbox” in which new propositions may be tested in a live environment with relaxations to certain rules for a limited time.

Spain

There is currently no specific insurance regulation on Blockchain and therefore it is necessary to rely on the general regulation on the subject.

In this regard, its regulation may be found in the following rules:

- Royal Decree-Law 7/2021 on the transposition of European Union directives in the areas of competition, prevention of money laundering, credit institutions, telecommunications, tax measures, prevention and repair of environmental damage, posting of workers in the provision of transnational services and consumer protection;
- Law 11/2021 on measures to prevent and combat tax fraud, transposing Council Directive (EU) 2016/1164 laying down rules against tax avoidance practices that directly affect the functioning of the internal market, amending various tax rules and on the regulation of gambling;
- Royal Legislative Decree 4/2015, approving the consolidated text of the Securities Market Law.

3. DIGITAL IDENTITY AND ONBOARDING DATA

Belgium



A distinction must be made as to whether the insurance distributor is an obliged entity or not in accordance with the Anti-Money Laundering regulations. If it is an obliged entity, the Belgian Anti-Money Laundering Law applies, as well as the Financial Services and Markets Authority (“FSMA”) guidelines.

If it is not an obliged entity, there are certain common practices in the sector such as developing a customer identification and recognition procedure.

In both cases, the Regulation 910/2014 applies on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC.

France

Any insurance contract must be preceded by a prior information of the insured in order to guarantee that the client is aware of the conditions and the price, the modalities are provided for in articles L. 222-1 and seq. of the French consumer code.

The customer identification procedure, also known as Know Your Client (“KYC”), for online onboarding changes whether the contract is a life insurance policy or not:

- if it is a life insurance policy, then article R. 561-5 of the French monetary and financial code imposes a reinforced double verification, notably by identifying the beneficial owner of the policy;
- in the case of any other insurance contract, article R. 561-14-2 of the French monetary and financial code requires simple identification of the client by providing an identity card.

Italy

There are no specific provisions on client digital identification nor regulations ruling onboarding procedures for Insurtech. However, the Public Digital Identity System (“SPID”) regulation laid down in the Legislative Decree no. 82/2005 “Digital Administration Code” might apply to Insurtech.

A number of points still remain under debate, such as the standardisation of customer identification procedures or those for signing contracts online. However, there is still no official guidance from the authorities on the correct use of such tools.

Portugal

The Law no. 83/2017 establishes the measures to combat money laundering and terrorist financing and partially transposes Directives 2015/849/EU of the European Parliament and of the Council of 20 May 2015 and 2016/2258/EU of the Council.

The financial entities are, in the terms of Law no. 83/2017, obliged to implement the identity verification and a due KNC system, according to which, before establishing a business relation, the following identification element must be provided:

***For private individuals:** (i) photograph; (ii) name; (iii) signature; (iii) birth date; (iv) nationality; (v) expiry date and issuer of identification document; (vi) job; (vii) full address; and (viii) place of birth.

***For legal persons:** (i) the object; (ii) address of registration; (iii) VAT; (iv) identification of the shareholders or directors; and (v) country of incorporation.

A second assessment must take place based on one of the following means of proof of identification:

- through videoconference in line with Regulation no. 2/2018 from the Bank of Portugal;
- means of electronic identification, qualified electronic signature; or secure authentication of the State through the card reading system; the Digital Mobile Key (“CMD”, from its name in Italian *Chiave mobile digitale*), under Law No. 37/2014, of 26 June, establishes an alternative and voluntary system of authentication of citizens in portals and websites;
- the use of interoperability platforms between the information systems issued by public services, in accordance with Regulation 910/2014 on electronic identification and trust services for electronic transactions in the internal market (“eIDAS”);
- the data subject's authorisation for transferring the data, pursuant Article 4-A (1) and (4) of Law 37/2014;
- access to the client's electronic identification or of equivalent value through the use of secure devices, recognised, approved or accepted by the competent authorities to provide qualified certification;
- through qualified trust service providers, from those listed by the National Cyber Security Office;
- the use of interoperable platforms between information systems, issued by public services.

The Netherlands

A distinction must be made as to whether the insurance distributor is an obliged entity according to the Dutch Anti-Money Laundering and Anti-Terrorist Financing Act, in Dutch: *Wet ter voorkoming van witwassen en financieren van terrorisme* (“WWFT”). In the Netherlands only life insurance distributors are subject to the WWFT. Such insurance distributors should ensure that the risks associated with digital onboarding are mitigated.

In any case, the insurance distributor is required to screen clients on possible sanctions as referred to in Dutch and international sanction legislation.

On 23 January 2018, the ESAs published their Opinion on the use of innovative solutions in the customer due diligence process. The DNB explicitly refers to this opinion in its Anti Money Laundering (“AML”) guideline a framework on how to apply innovation techniques in customer due diligence procedures and rules.

On 18 October 2022, the Dutch Trade and Industry Appeals Tribunal (“CBb”), the highest economic administrative court in the Netherlands, issued an important ruling concerning the use of innovation techniques and artificial intelligence for AML purposes. The CBb ruled that the WWFT does not prescribe exactly how the screening requirements following from the WWFT must be fulfilled and that also digital tools and innovation techniques may be used in order to be compliant with the WWFT. The ruling has been issued in relation to an online Dutch bank (a FinTech), but may also have relevance for other financial institutions (e.g. Insurtech) that make use of innovate techniques for onboarding or transaction monitoring purposes.

Ukraine

There are no specific rules on digital identification and online onboarding of clients for insurance providers. The insurers thus abide by general rules of Ukrainian law and applicable rules depend on the transactions that such insurer will carry out with the client. For example, under the Law of Ukraine “On Prevention and Counteraction to Legalisation (Laundering) of Proceeds from Crime, Terrorism Financing and Financing of Proliferation of Weapons of Mass Destruction” No. 361-IX, dated 6 December 2019, insurers are defined as the subject of the initial financial monitoring. This implies that insurers are required to proceed with the identification and regular duly checks of their new and existing clients. Such checks can happen both in person and remotely (i.e., online).

The specific requirements as to the identification procedure (including digital identification) should be defined by internal policies of insurers depending on their size and business model, as well as size and business model of their client. For individuals in retail insurance, such checks would typically be limited to checking of ID only.



United Kingdom

First an assessment must be made as to whether the relevant firm is a ‘relevant person’ for the purposes of the Money Laundering, Terrorist Financing and Transfer of Funds (Information on the Payer) Regulations 2017 (“MLRs 2017”). If so, digital identification and onboarding will need to be carried out in accordance with the MLRs, with due regard to be paid to the guidance set out by the Joint Money Laundering Steering Group.

Due consideration should also be given to the requirements of:

- The Proceeds of Crime Act 2002
- The Terrorism Act 2000
- The rules and guidance contained in the Senior Management Arrangements, Systems and Controls sourcebook of the FCA Handbook.

In relation to electronic identification, the UK has retained elements of eIDAS by virtue of the Electronic Identification and Trust Services for Electronic Transactions (Amendment etc.) (EU Exit) Regulations 2019. Consideration should also be given to the Electronic Identification and Trust Services for Electronic Transactions Regulation 2016.

Note that, for the purposes of eIDAS, trust service providers established in the UK are now third country trust service providers, can no longer provide ‘qualified trust services’ in the EU, and UK electronic identification schemes notified prior to 1 January 2021 are no longer recognised by EU member states.

Spain

A distinction must first be made as to whether the insurance distributor is an obliged entity or not in accordance with the Anti-Money Laundering regulations. If it is an obliged entity, the following will apply:

- Law 10/2010, on the prevention of money laundering and the financing of terrorism;
- Royal Decree 304/2014, approving the Regulation of Law 10/2010, of 28 April, on the prevention of money laundering and the financing of terrorism;
- Authorisation of video-identification procedures by Executive Service of the Commission for the Prevention of Money Laundering and Monetary Offences (“SEPBLAC”) on 11 May 2017.
 - In case it is not an obliged entity, there are certain common practices in the sector such as to develop a customer identification and recognition procedure.
 - In both cases it is also applicable the Regulation 910/2014, on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC.

4. DATA PROTECTION



The processing of personal data by insurers can be categorised as “particularly sensitive”. According to the *Regulation (EU) 2016/679 Of The European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (“GDPR”)*, sensitive data includes data that reveals racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data intended to uniquely identify a natural person, data concerning health or sex life or sexual orientation.

Furthermore, if the entity considered as the controller processes personal data on the basis of the data subject's consent, it must be able to demonstrate that the data subject has given their consent.

Insurtech fall under the scope of all these data protection rules when transferring data. Consequently, a number of concerns arise for Insurtechs in relation to online insurance distribution.

Belgium

The main issues that may arise include, but are not limited to:

Having the appropriate measures and policies in place to comply with legal requirements such as deleting data as soon as it is no longer needed, keeping a processing activities register, notifying cyber-attacks and appointing a data protection officer.

Organising document management systems in order to identify the information given to each customer and when this information was given.

Attention should be paid to non-discrimination principle during the application of actuarial pricing schemes.

Sharing of information with the UK, which is now outside the EU.

France

As French law does not specifically regulate the processing of personal data by insurance companies and intermediaries, the GDPR applies. In relation to online distribution, the mains issues may be as follows:

- Identifying the status of actors: in principle, an insurer is the data controller for processing anything related to the performance of an insurance contract. However, the broker and the insurer could be joint controllers if both determine the purpose and the essential means of processing.
- Determining the legal basis for each purpose. The process should be based on the insurance contract, provided that the processing is strictly necessary for the performance of the contract, or the legitimate interest. For specific cases, the user consent may be mandatory (e.g. for some processing of health data or for commercial prospecting under Art. L34-5 of the French Post and Electronic Communications Code). In any event, insurance companies should not use data collected for a subsequent purpose.
- Limiting the storage period: when an insurance contract is concluded, certain specific limitation periods may apply (e.g. the Insurance Code provides with a limitation period of 30 years from the death of the insured for life insurance contracts).
- Respect for transparency and individuals' rights: individuals must be informed of the use of their data, as well as of their rights (to access, rectifying, oppose, delete data etc). They must also be able to exercise these rights electronically. If the insurance organisation uses data profiling, it must be subject to (i) transparency requirements; and (ii) specific conditions if it is part of an automated decision-making process.

- Securing data: All the necessary measures must have been taken to guarantee the security of the data (physical or computer security, securing the premises, managing authorisations and computer access rights, limiting access to data only by third parties authorised by law). These measures must adapt to the sensitivity of the data (e.g. health data or the National Identification Registry or “NIR”).

Italy

There is no specific regulation regarding the processing of personal data by insurance companies and intermediaries. However, general principles set forth in the GDPR and the Legislative Decree no. 196/2003 “Italian Privacy Code” apply to Insurtech as well. The main issues that may arise include:

- Implementing the appropriate technical and organizational measures in place to ensure a level of security appropriate to the risk.
- Keeping a record of processing activities.
- Ensuring data is only retained for as long as is necessary.
- Within the limit stated by the GDPR, notifying the competent Data Protection Authority of data breaches including cyber-attacks and communicating it to the data subjects.
- Appointing a Data Protection Officer.
- Carrying out Data Protection Impact Assessments activities, when mandatory according to the GDPR and Decision 467/2018 of the Italian Data Protection Authority (the “Garante”).
- Ensure to rely on a proper legal basis for processing personal data, in particular, if special categories of data are processed.
- Respect the transparency principles by informing the data subjects about the use that will be made of their data and their rights.

Portugal

The main issues to consider include, but are not limited to:

- Compliance with applicable data protection laws meaning GDPR, as well as the Law of Execution (Law no. 58/2019).
- Having appropriate measures in place to ensure compliance with such applicable data protection laws such as keeping a register of processing activities, ensuring data is only retained for as long as is necessary, thereafter being securely deleted, notifying security breaches including cyber-attacks and the appointment of a data protection officer.
- Ensure compliance with the GDPR, specifically article 22, for automated decision-making processes.
- Transparency and adequate information (Article 13(2), f)),
- Compliance with the right to an explanation which can be particularly challenging given algorithmic opacity. Even so, the considered explanation must:
 - Inform and assist the data subject to understand a particular decision;
 - Provide grounds for contesting;
 - Understand what could be changed based on the decision-making process.
- Implement reinforced security measures, namely by deploying cryptography-based solutions.
- Implementing document management systems to be able to evidence what information is provided to each customer, when it was provided and on what basis.



- Being aware of the risk of unlawfully discriminating against customers and putting in place measures to mitigate these risks.

The Netherlands

There is no local legislation covering specific issues in this context. The main issues that may arise include, but are not limited to:

- Having in place the appropriate procedures to comply with legal requirements such as data deletion, keeping a register of processing activities, cyber-attacks notifications and the appointment of a data protection officer.
- Organising document management systems in order to identify and prove the information provided to each customer and when this information was given.
- Special attention to the principle of non-discrimination in the application of actuarial pricing schemes.

Ukraine

The main issues for insurance companies and intermediaries in Ukraine include:

- Compliance with legal requirements such as notification of personal data processing to the special officer, notification of actions with personal data and deleting data as soon as it is no longer needed, etc.
- Adapting privacy systems and processes in light of the upcoming data protection reform in Ukraine.
- Compliance with confidentiality policies and other data protection documents on websites or other online resources.

United Kingdom

The main issues to consider include, but are not limited to:

- Compliance with applicable data protection laws meaning Data Protection Act 2018 (“DPA 2018”), UK GDPR (having the meaning given in the DPA 2018), Privacy and Electronic Communications Regulations (“PECR”) compliance and adhering to applicable guidance and codes issued by the Information Commissioner’s Office (“ICO”).
- Having appropriate measures in place to ensure compliance with applicable data protection laws such as keeping a register of processing activities, ensuring data is only retained for as long as is necessary, (thereafter being securely deleted), notifying of security breaches including cyber-attacks and the appointment of a data protection officer;
- Implementing document management systems to be able to evidence what information is provided to each customer, when this was provided and on what basis;
- Being aware of the risk of unlawfully discriminating against customers by using actuarial pricing schemes and putting measures in place to mitigate the risk.

Spain

Given mandatory enforcement for all parties that process personal data, Insurtechs must comply with all data protection rules when transferring data.

Due to the nature of activities undertaken by insurers, their processing of personal data can be categorised as “particularly sensitive”. GDPR singles out data that reveals racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, biometric data intended to uniquely identify a natural person, data concerning health or sex life or sexual orientation.

If the controller processes personal data on the basis of the data subject's consent, it must be able to demonstrate that data subjects have given their consent.

The main issues that may arise include, but are not limited to:

- having the appropriate means in place to comply with the legal requirements such as deleting data as soon as it is no longer needed, keeping a register of processing activities, notifying cyber-attacks and the appointment of a data protection officer;
- organising document management systems in order to prove what information was given to each customer and when this information was provided;
- special attention must be paid to the principle of non-discrimination in the application of actuarial pricing schemes.

5. OPEN INSURANCE AND APIS

The Open Insurance framework offers potential benefits for consumers and insurers, since greater availability of data should lead to improved risk monitoring and assessment, a better customer experience and increased fraud detection. Additional access to data generated by both public and private sectors could also provide the opportunity to increase innovation and competition in the insurance sector. At the same time, it will be important to safeguard consumers' ownership of their data and to ensure that data sharing is consent-based.

The sharing of personal data and web services is a new concept in the insurance industry that should, however, have a very positive impact on the Insurtech market. This process is known as "APIfication", i.e. insurers themselves becoming digitisation-driven and opening up their APIs (web services) to all Insurtech operators, so that any market player can access this data and information.

Operating within the scope of legal certainty is problematic given that regulation on this matter has not yet been enacted in Europe. Therefore elaboration on the exact scope and objectives of such a framework is necessary.

Belgium

There are still no codes of conduct or guidelines on Open Insurance.

Nevertheless, in January 2021 EIOPA issued a discussion paper on "*Accessing and Sharing Insurance-Related Data Discussion Paper*", so it is conceivable that further developments will be introduced on this subject.

France

The sharing of information through APIs in the insurance sector has not been specifically regulated at national level.

According to the last report of the French Prudential Supervision and Resolution Authority ("ACPR") of January 2022, "for several insurers, the portability remains a marginal subject which is still at an early stage (lack of demand from customers, lack of industrialised solutions, lack of technical standards and standardised formats). However, some projects are underway, with data API projects to ensure interoperability between the front and back office and to accelerate the opening of services to partners, as well as data hub projects to share data".

Italy

While the use of new technologies such as AI, blockchain or APIs is increasingly widespread and IVASS is monitoring this trend, there is still no official guidance from the authorities on the correct use of such tools.

Portugal

There is no current legislation, official guidance nor any kind of code of conduct in place on Open Insurance. Furthermore, there is still no position taken by the Portuguese regulator ASF regarding this matter.

The Netherlands

No local legislation, codes of conduct, or guidelines exist on open insurance and information sharing through API.

Though, on 8 June 2021, the AFM published an explanatory study on “*The personalisation of prices and conditions in the insurance sector*”. In this study, the AFM describes, analyses, and identifies the development and use of personalised premiums and policy conditions in the Dutch insurance sector, with a focus on non-life insurance.

From an EU law perspective, the EIOPA's discussion paper on “*Accessing and sharing Insurance-Related Data Discussion Paper*” published in January 2021, has significance.

Ukraine

There is currently no specific legislation, official guidance and/or a code of conduct aimed at governing the sharing of information through API.

Meanwhile, information that is collected or shared through API, may include personal data, among others. In such a case, processing of personal data is subject to general Ukrainian data protection law requirements.

Market participants are currently discussing ways to share information about insureds between different stakeholders (e.g., between insurer and medical facility). These talks however have not yet materialised into specific legislative proposals.

United Kingdom

There is currently no legislation or codes of conduct in place on Open Insurance.

However, the UK government published “*The Kalifa Review on Fintech*” in February 2021, an independent report that included recommendations on how to bring the Open Insurance project to life to support growth and create a framework for innovation.

The FCA published its feedback statement (FS21/7) addressing the opportunities and challenges raised by Open Insurance and setting out its proposals for the future. It suggests that a legislative framework will need to be put in place to develop Open Insurance, but this is yet to be determined.

Spain

There are still no codes of conduct or guidelines on Open Insurance.

Nevertheless, in January 2021 EIOPA issued a discussion paper on “*Accessing and Sharing Insurance-Related Data Discussion Paper*”, so it is conceivable that further developments will be introduced in this subject.

6. BIG DATA

Belgium

There is no specific legislation in place, nor official guidance or a code of conduct expressly governing the use of Big Data by insurance companies and intermediaries.

France

In terms of code of conduct, there are no specific legal provisions on Big Data that have been enforced. However, GDPR guidelines published by the French Insurance Federation on July 2021 helps the industry to better deal with the main issues identified on Big Data usages.

As regards legislation:

- As mentioned in Section 4.1, GDPR provides specific conditions for data profiling when assessing insurance, especially if it is part of an automated decision-making process. Please also refer to other GDPR rules on data processing;
- The Decree No. 2019-341 lists the authorised use of the national identification registry (“NIR”), in particular by insurance organisations (e.g. social protection, entering, managing and executing insurance



contracts, compliance with obligations relating to the fight against money laundering and the financing of terrorism or to the fight against fraud).

The National Assembly proposed, on 23 January 2019, a bill prohibiting the use of personal data collected by internet of things (“IoT”) in the field of insurance, especially for data relating to the lifestyle and health of persons. However, this law has still not been enacted.

Italy

There is not specific legislation in place, nor official guidance or a code of conduct expressly governing the use of Big Data by insurance companies and intermediaries.

Portugal

Currently there is no legislation specifically governing the use of Big Data by insurance companies and intermediaries nor any specific code of conduct.

The only Guideline available on this matter is a Report of the Joint Committee of the European Supervisory Authorities, which provides that financial entities deploying Big Data-driven tools must implement mitigating measures, acknowledge the risks for consumers and the difficulties resulting from having a wider knowledge of the client.

As such, the following adequate guarantees must be taken into consideration, namely:

- Clients need to give their free and express consent for their data to be processed;
- Financial institutions must provide all necessary information about the financial products and the underlying use of Big Data;
- Reinforced security measures must be taken, in particular, when considering the sensitivity of the processed information.

The Netherlands

The following local standards and guidelines apply to the use of big data by insurance companies and intermediaries:

- Code of Conduct for the Processing of Personal Data by Insurers published in 2018 by the Dutch Association of Insurers (in Dutch: *Verbond van Verzekeraars*);
- Ethical framework for data-driven applications by insurers for members of the Dutch Association of Insurers published in 2021; and
- Act of 16 May 2018, containing rules on the implementation of GDPR (in Dutch: *De Nederlandse Uitvoeringswet AVG, UAVG*).

Ukraine

There is currently no legislation, official guidance and/or a code of conduct specifically aimed at governing Big Data by insurance companies and intermediaries.

United Kingdom

At present there is no legislation specifically governing the use of Big Data by insurance companies and intermediaries nor any specific code of conduct.

The UK regulator has acknowledged the potential for positive consumer outcomes resulting from the use of Big Data, but has also highlighted how its use may result in some consumers experiencing difficulty in obtaining insurance, and has expressed pricing concerns. The UK regulator has reminded firms of their obligation to ensure that any use of data is in line with data protection legislation and guidelines from the ICO.

The UK regulator has also raised concerns over the potential impact of Big Tech firms entering the insurance market. Again, it has acknowledged the potential positive impact this may have, particularly in introducing efficiencies to the value chain. However, it has noted that competition concerns may arise as a result of the

manner in which data gathered by Big Tech firms from their wider business is used in the underwriting process.

When using Big Data in the development and distribution of insurance products firms should be mindful of their duty to act in the customers' best interests and the rules and guidance around ensuring fair value. The introduction of the new Consumer Duty is also likely to be pertinent to firms' use of Big Data.

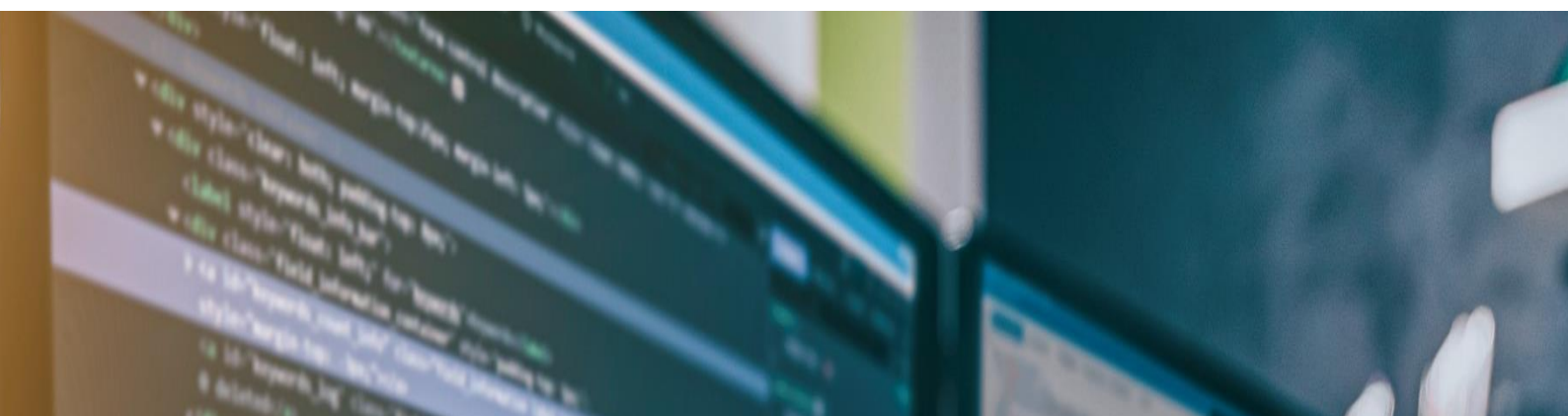
The following legislation, standards and guidelines apply generally to Big Data due to its close relationship with Data Protection:

- DPA 2018, UK GDPR (having the meaning given in the DPA 2018), PECR compliance.
- Accordingly, key principles of data protection laws apply: (i) lawfulness, fairness and transparency; (ii) purpose limitation; (iii) data minimisation; (iv) accuracy; (v) storage limitation; (vi) integrity and confidentiality (security); and (vii) accountability.
- The ICO has issued Guidance on AI and data protection which covers Big Data, the main takeaway being to consider data protection at an early stage when carrying out any projects using Big Data.

Spain

The following standards and guidelines shall apply to Big Data due to its close relationship with Data Protection:

- Organic Law 3/2018, on the Protection of Personal Data and guarantee of digital rights;
- The Code of good practices in data protection for Big Data projects published by the Spanish Data Protection Agency ("AEPD").



Legal schedule



| No. | EU country | Rule name |
|-----|------------|---|
| 1. | Belgium | Anti-Money Laundering Law of 18 September 2017, Belgian Anti-Money Laundering Law. |
| | | Directive (EU) 2015/2366, Payment Services Directive 2. |
| | | Regulation 910/2014, on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC. |
| | | Legislation on distance financial contract and the 2002 law on information society services and electronic commerce. |
| 2. | France | July 2021: GDPR guide published by the French Insurance Federation. |
| | | Decree No. 2019-341 of 19 April 2019. |
| | | French Post and Electronic Communications Code of 27 April 2017. |
| | | Regulation (EU) 2016/679 (GDPR). |
| | | Ordinance No. 2016-301 of March 14, 2016, on the Legislative part of the Consumer Code. |
| | | 2000-1223 of 14 December 2000; French monetary and financial code. |
| | | 91-716 of 26 July 1991; French insurance code. |
| 3. | Italy | 6 January 2022, EIOPA report on the application of the Insurance Distribution Directive ("IDD"). |
| | | Decree 100/2021 issued by the Ministry of Economy and Finance, implementing the delegated act envisaged under Decree Law 34/2019 ('Growth Decree'), sets out the 'FinTech Committee rules and experimentation. |
| | | D.M. 30.04.2021, no. 100, Regulation implementing article 36, paragraphs 2-bis and following, of the legislative decree 30.04.2019, n. 34, converted, with modifications, by the law 28.06.2019, n. 58, on the discipline of the Committee and FinTech experimentation. |
| | | Italian Legislative Decree 30.04.2019, n. 34, Urgent measures for economic growth and for the resolution of specific crisis situations, converted into L. 28.06.2019, n. 58 |

| No. | EU country | Rule name |
|-----|------------|---|
| | | Law Decree no. 135/2018 defines blockchain and smart contracts (<i>Decreto-Legge 14 dicembre 2018, n. 135 Disposizioni urgenti in materia di sostegno e semplificazione per le imprese e per la pubblica amministrazione</i>). |
| | | Legislative Decree 7 March 2005, no. 82 (Digital Administration Code) |
| | | Legislative Decree 15.12.2017, no.218, Implementation of Directive (EU) 2015/2366 relating to payment services in the internal market |
| | | Regulation of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, 27.04.2016, 2016/679/UE (GDPR) implemented in Italy with Italian Legislative Decree no. 101/2018 ("Italian Legislative Decree 10.08.2018, no. 101, Provisions for the adaptation of national legislation to the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27.04.2016, relating to the protection of individuals with regard to the processing of personal data, as well as the free circulation of such data and repealing Directive 95/46 / EC (GDPR)") |
| | | Italian Legislative decree of 07.09.2005 n. 209, Italian Private Insurance Code |
| | | Legislative Decree 6.09.2005, n. 206, Consumer Code |
| | | Decree Law no.109-G/2021, of 10 December (transposing partially the Directive (EU) 2019/2161 of the European Parliament and of the Council, of 27 November, with respect to the better enforcement and modernisation of Union consumer protection rules). |
| 4. | Portugal | ASF's Regulatory Rule no.13/2020-R, of 30 December. |
| | | Law No 58/2019, which ensures the implementation in Portugal of GDPR. |
| | | Law no. 7/2019, of 16 January, which implemented the EU Insurance Directive, and sets forth important regime innovations applicable to insurers/reinsurers and distributors operating in Portugal (in Portuguese, "Lei n.º 7/2019, de 16 de janeiro (a Lei 7/2019), que implementou a Diretiva 2016/97/UE, de 20 de janeiro de 2016 (a DDS)", revogando e anterior regime, vertido no Decreto-Lei 144/2006, de 16 de janeiro (o DL 144/2006)"). |
| | | Decree Law no. 91/2018, of 12 November, which regulates the Legal Framework for Payment Services and Electronic Currency (transposing the Payment Services Directive (EU) 2015/2366 of the European Parliament and of the Council, of 25 November). |
| | | Regulation no. 2/2018 from the Bank of Portugal. |
| | | Law no. 83/2017, of 18 August, establishes the measures to combat money laundering and terrorist financing and partially transposes Directives 2015/849/EU of the European Parliament and of the Council of 20 May 2015 and 2016/2258/EU of the Council of 6 December 2016. |

| No. | EU country | Rule name |
|-----|-----------------|---|
| | | Regulation 910/2014 on electronic identification and trust services for electronic transactions in the internal market ("eIDAS"). |
| | | Law No. 37/2014, of 26 June, establishing an alternative and voluntary system of authentication of citizens on public administration websites and other Internet sites, called Digital Mobile Key. |
| | | Decree Law no. 95/2006, of 29 May, transposing the Directive concerning distance marketing of consumer financial services. |
| | | Decree Law no. 7/2004, of 7 January, which regulates the Legal Framework for Electronic Commerce (transposing the Directive (EU) 2000/31/CE, of the European Parliament and of the Council, of 8 June). |
| | | Consumer Act (Law no. 24/96, of 31 of July). |
| | | 8 June 2021, the AFM published an explanatory study on "The personalisation of prices and conditions in the insurance sector". |
| 5. | The Netherlands | Ethical framework for data-driven applications by insurers for members of the Dutch Association of Insurers published in 2021. |
| | | April 2020 "Theme research Insurtech" DNB. |
| | | 25 July 2019; exploratory study on " <i>Artificial intelligence in the insurance sector</i> " AFM and DNB. |
| | | Act of 16 May 2018, containing rules on the implementation of the GDPR (in Dutch: "De Nederlandse Uitvoeringswet AVG, UAVG"). |
| | | Code of Conduct for the Processing of Personal Data by Insurers published in 2018 by the Dutch Association of Insurers (in Dutch, "Verbond van Verzekeraars"). |
| | | 23 January 2018, the ESAs have published their "Opinion on the use of innovative solutions in the customer due diligence process". |
| | | Payment Services Directive II (2015/2366), which is mainly implemented in the Netherlands into the Dutch Financial Supervision Act. |
| | | 1 August 2008, Dutch Anti-Money Laundering and Anti-Terrorist Financing Act (in Dutch " <i>Wet ter voorkoming van witwassen en financieren van terrorisme</i> "). |
| | | 1 January 2007, Decree on Conduct of Business Supervision of Financial Undertakings (in Dutch " <i>Besluit Gedragstoezicht financiële ondernemingen</i> "). |
| | | 28 September 2006, Dutch Financial Supervision Act (in Dutch " <i>Wet op het financieel toezicht</i> "). |
| | | 1992, Dutch Civil Code (in Dutch " <i>Burgerlijk Wetboek</i> "). |

| No. | EU country | Rule name |
|-----|----------------|--|
| 6. | Ukraine | Regulation of the Law of Ukraine "On Payment Systems and Funds Transfer in Ukraine" No. 2346-III, dated 5 April 2001, which relatively soon will be replaced by the new Law of Ukraine "On Payment Services" 1591-IX, becoming effective on 1 August 2022. |
| | | Law of Ukraine "On Virtual Assets", on 8 September 2021. |
| | | Law of Ukraine "On Prevention and Counteraction to Legalization (Laundering) of Proceeds from Crime, Terrorism Financing and Financing of Proliferation of Weapons of Mass Destruction" No. 361-IX, dated 6 December 2019. |
| | | Law of the Ukraine "On Insurance", adopted on 7 March 1996 under No. 85/96-BP. |
| | | September 2021, National AI Strategy (UK government). |
| 7. | United Kingdom | Electronic Identification and Trust Services for Electronic Transactions (Amendment etc.) (EU Exit) Regulations 2019. |
| | | July 2019, FCA Policy Statement PS19/22. |
| | | Data Protection Act 2018 ("DPA 2018"), UK GDPR. |
| | | Payment Services Regulations 2017/752, transposing the Payment Services Directive. |
| | | Money Laundering, Terrorist Financing and Transfer of Funds Regulations 2017 ("MLRs 2017"). |
| | | Electronic Identification and Trust Services for Electronic Transactions Regulation 2016. |
| | | ICOBS sourcebook of the FCA Handbook. |
| | | Consumer Rights Act, 2015 |
| | | Regulation 910/2014 on electronic identification and trust services for electronic transactions in the internal market ("eIDAS"). |
| | | Proceeds of Crime Act 2002. |
| | | Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. |
| | | Terrorism Act 2000. |
| 8. | Spain | Law 11/2021 of 9 July on measures to prevent and combat tax fraud, transposing Council Directive (EU) 2016/1164 of 12 July 2016 laying down rules against tax avoidance practices that directly affect the functioning of the internal market, amending various tax rules and on the regulation of gambling. |

| No. | EU country | Rule name |
|-----|------------|---|
| | | Royal Decree-Law 7/2021 of 27 April on the transposition of European Union directives in the areas of competition, prevention of money laundering, credit institutions, telecommunications, tax measures, prevention and repair of environmental damage, posting of workers in the provision of transnational services and consumer protection. |
| | | Royal Legislative Decree, 3/2020, of 4 February, on urgent measures transposing into Spanish law various European Union directives in the field of public procurement in certain sectors. |
| | | Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights. |
| | | Royal Legislative Decree 19/2018, of 23 November, on payment services and other urgent measures in financial matters, transposing the Payment Services Directive. |
| | | Royal Legislative Decree 4/2015, of 23 October, approving the consolidated text of the Securities Market Law. |
| | | Regulation 910/2014, on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC. |
| | | Royal Decree 304/2014, of 5 May, approving the Regulation of Law 10/2010, of 28 April, on the prevention of money laundering and the financing of terrorism. |
| | | Law 10/2010, of 28 April, on the prevention of money laundering and the financing of terrorism. |
| | | Royal Legislative Decree 1/2007, of 16 November, approving the revised text of the General Law for the Defence of Consumers and Users and other complementary laws. |
| | | Law 22/2007 of 11 July 2007 on distance marketing of consumer financial services. |
| | | Law 34/2002 of 11 July 2002 on information society services and electronic commerce. |

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